REMARKS

Claims 1, 3-7, 9 and 11 are pending in this application. Claims 2 and 10 were previously canceled. Claim 8 was previously withdrawn without prejudice. Applicants reserve the right to file one or more continuation, divisional, or continuation-in-part applications directed to any withdrawn subject matter. Claim 1 is amended to replace "animal" with "dog or cat", consistent with the previous amendment. Claims 3-7 are amended to correct the dependency from claim 2 to claim 1, consistent with the previous amendment where the limitations of claim 2 were added to claim 1 and claim 2 was canceled. These amendments are purely formal and should not be considered to present any new issues for examination. No new matter is added. Applicants respectfully request entry of the amendments.

I. The rejection under 35 U.S.C. § 103(a) should be withdrawn

Claims 1, 3-7 and 9-11 are rejected as allegedly obvious under 35 U.S.C. § 103(a) over Ishihara (US 6297280)[1] in view of Reisbick *et al.*, Handbook of Essential Fatty Acid Biology: Biochemistry, Physiology, and Behavioral Neurobiology: Chapter 17 pp. 397-426 ("Reisbick"). Applicants respectfully traverse this rejection.

The framework for analysis as to the obviousness of chemical formulations and their uses is similar to that involving novel compounds. *Unigene Laboratories, Inc. et al. v. Apotex, Inc., et al.*, No. 2010-1006, slip op. at 13-16 (Fed. Cir. August 25, 2011). First, a lead or reference formulation is identified from the art, and then a flexible teaching-suggestion-motivation (TSM) test is applied to determine whether the modifications would be obvious. *Id.*

Assuming one of skill in the art would start with providing formulations as disclosed by Ishihara, the Examiner concedes that Ishihara does not disclose the claimed ranges for DHA and/or EPA. The Examiner merely states in a conclusory way that it would be obvious to adjust the dosage of DHA and/or EPA. But as stated in MPEP 2144.05:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)

[1] Applicants note that although claim 10 was previously canceled, it was nevertheless included in the rejection, apparently in error. Applicants request confirmation that the last set of amendments were entered. Also the Office Action citation for "Ishihara" is to US 6279280, which is a patent directed to "an aesthetic security doorway", not US 6729280, which Applicants assume is what was intended.

Because neither of the references cited provide any teaching, suggestion or motivation to modify the DHA/EPA levels to the claimed ranges, they do not make the claimed methods obvious.

Because the Examiner has not identified any portion of the cited references that discloses or suggests the intent to practice the claimed methods for the purpose recited in the claims, or which provides motivation to optimize the formulations of Ishihara for that purpose, the Examiner has not established *prima facie* obviousness. As the M.P.E.P. states, "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." (M.P.E.P. § 2141). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* Applicants respectfully submit that the Examiner has failed to put forward sufficient articulated reasons as to why Applicants' claims are obvious in view of the cited references.

A. Neither Ishihara nor Reisbick teach that DHA or EPA levels are result-effective variables for influencing behavior and moreover Ishihara discloses only supplements which would provide a diet with DHA or DHA/EPA levels far below the levels of the claims

The pending claims encompass methods for influencing behavior in a dog or cat, the methods comprising systemically administering to the animal in need thereof ***a diet*** comprising at least about 2% by weight of an omega-3 fatty acid or mixture of omega-3 fatty acids selected from the group consisting of eicosapentaenoic acid and docosahexaenoic acid as measured on a dry matter basis.

Ishihara is directed to supplements to be added to an animal's diet, which supplements contain theanine (a compound found in tea) and may optionally further comprise unsaturated fatty acids. Ranges for the amount of unsaturated fatty acids are not provided. The electrolyte solutions of Table 1 of Ishihara contain no fatty acids, but are claimed to be effective, as are many of the fatty acid-free supplements. Some of the examples of supplements contain DHA in small amounts, provided in the form of a powder made from egg yolks, having 5% DHA. The amounts of DHA in the exemplified formulations of Ishihara Example 4 are as follows:

A-I test example 1 (dogs)

A: None disclosed

B: 5mg/day (from 100 mg/day of powder with 5% DHA)

C: None disclosed

D: None disclosed

E: None disclosed

F: None disclosed

G: 0.9 mg/day (from 18 mg/day of powder with 5% DHA)

H: 365 mg/day (from 7.3 g/day of powder with 5% DHA)

I: None disclosed

AA-II – test example 2 (cats)

AA: None disclosed

BB: 4.15 mg/day (from 83 mg/day of powder with 5% DHA)

CC: None disclosed

DD: None disclosed

EE: None disclosed

FF: None disclosed

GG: 0.75 mg/day (from 15 mg/day of powder with 5% DHA)

HH: 300 mg/day (from 6 g/day of powder with 5% DHA)

II: None disclosed

AAA-III – test example 3 (dogs)

AAA: None disclosed

BBB: 5.5 mg/day (from 110 mg/day of powder with 5% DHA)

CCC: None disclosed

DDD: None disclosed

EEE: None disclosed

FFF: None disclosed

GGG: 1 mg/day (from 20 mg/day of powder with 5% DHA)

HHH: 385 mg/day (from 7.7 g/day of powder with 5% DHA)

III: None disclosed

J-R test example 4 (dogs)

J: None disclosed

K: 5.5 mg/day (from 110 mg/day of powder with 5% DHA)

L: None disclosed

M: None disclosed

N: None disclosed

O: None disclosed

P: 1 mg/day (from 20 mg/day of powder with 5% DHA)

Q: 385 mg/day (from 7.7 g/day of powder with 5% DHA)

R: None disclosed

JJ-RR test example 5 (dogs)

JJ: None disclosed

KK: 6.5 mg/day (from 130 mg/day of powder with 5% DHA)

LL: None disclosed

MM: None disclosed

NN: None disclosed

OO: None disclosed

PP: 1.25 mg/day (from 25 mg/day of powder with 5% DHA)

QQ: 440 mg/day (from 8.8 g/day of powder with 5% DHA)

RR: None disclosed

Thus, the highest total amount of DHA provided to the diet using the supplements of Ishihara is less than half a gram (formulation QQ), and for most of the examples, it is absent or much lower. For even formulation QQ to provide 2% DHA to an animal's diet, the animal would receive only 22 g/day of food, i.e., less than one ounce per day of food. Even a relatively small dog or cat would likely be expected to eat more than an ounce of food a day. Accordingly, it is evident that the formulations of Ishihara do not provide a diet comprising DHA and EPA at levels approaching those set forth in the claims.

Applying the analysis as required by *Unigene,* discussed above, the Examiner has not identified any particular reason to start with the formulation in Ishihara having the highest DHA levels when other formulations with lower DHA levels work as well or better. Moreover, even if, for example formulation QQ was identified as the lead formulation, there is no motivation to

increase the levels of DHA or EPA based on the teachings of Ishihara. The higher DHA formulations do not provide appreciably better results than formulations having less DHA. There is no trend or support in the data that increasing the levels of DHA and/or EPA to the levels claimed would have any beneficial effect. Ishihara does not identify DHA or other fatty acids as having any effect on the dog's behavior by themselves. Although it is suggested that they could enhance the activity of the theanine (see, e.g., Ishihara, col. 2, ll. 57 et seq.), this is not well supported by the data provided. Nothing in Ishihara identifies the levels of DHA or unsaturated fatty acids as being a "result effective variable" in influencing behavior by themselves, and the data would not suggest this. Cf. *In re Antonie*, discussed above.

The secondary reference, Reisbick, does not cure this deficiency. Reisbick is a general review article regarding nutrition and behavior. It does not focus specifically on behavior of dogs or cats, nor does it address the deficiencies of Ishihara regarding selection of optimal formulations. Reisbick's conclusion is that

> "Determining how omega-3 FA affect behavior will require experiments that differentiate possible mechanisms of action, including effects on membrane function or prostaglandin metabolism, either of which may be central or peripheral. We have presented one hypothesis – that a decrease in dopamine and/or dopamine receptors in the prefrontal cortex of deficient animals increases their receptivity to environmental stimuli. This hypothesis provides a possible alternative explanation for some of the previous results which have been interpreted as effects on learning."

Reisbeck at p. 419-420. Fairly read, Reisbick is at most an invitation to experiment. It would not provide a reasonable expectation of success in predicting that a particular diet would have a particular effect in a particular species. There is a huge gap between the general suggestion that omega-3 fatty acids may affect dopamine function in some mammals, and the specific claims in this case that particular levels of particular fatty acids in the diet of particular species will affect their behavior in particular ways.

Moreover, Reisbick is a secondary reference, and it is not from the field of pet nutrition or pet behavior. As the Federal Circuit recently re-confirmed, for art to be asserted in a rejection under 35 U.S.C. §103, it must be analogous art. In the recent decision of *In re Klein*, ___ F.3rd ___ (Fed. Cir. 2011)(Slip op. 2010-1411, June 6, 2011), the Federal Circuit reversed the BPAI, finding that the claimed invention was not obvious because the references cited were not analogous art, as despite the structural similarity of the prior art products and the claimed product, they were not

specifically directed to the particular problem addressed by the applicant. In this case, the Examiner has not provided any motivation why one of skill in the art starting with Ishihara would even be motivated to turn to the very general disclosures of Reisbick, which do not address the particular problem of improving pet behavior, without the benefit of hindsight provided by the instant application.

Conclusion

For at least the foregoing reasons, Applicants respectfully submit that the rejection of claims 1, 3-7, 9 and 11 as obvious under 35 U.S.C. § 103 is improper and should be withdrawn. Applicants respectfully submit that the rejection under 35 U.S.C. §103 should be withdrawn and request that a formal Notice of Allowance be issued as to the pending claims. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

In the event that a fee is due for entry of this response, the Director of the United States Patent and Trademark Office is authorized to charge Deposit Account 50-2957 for any the fees necessary for entry of this response, and to credit that account with any refunds due.

Respectfully submitted,

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